

VIA ELECTRONIC MAIL: lunn@niehs.nih.gov

September 28, 2009

Dr. Ruth Lunn, Director
RoC Center
NIEHS MD K2-14
P.O. Box 12233
Research Triangle Park, NC 27709

RE: ***Johns Manville's Comments on Expert Panel Recommendations for
Glass Wool Fibers – 74 Fed. Reg. 40,598 (August 12, 2009)***

Dear Dr. Lunn:

Johns Manville (JM) appreciates the opportunity to submit comments on the recommendations from the June 9 – 10, 2009, Expert Panel on the listing status for glass wool fibers in the 12th Report on Carcinogens ("RoC") and the scientific justification for the recommendations.

JM has been an active participant in the 12th RoC process having submitted comments to the National Toxicology Program ("NTP") on several previous occasions, including comments on the draft Background Document entitled "*Commentary on NTP Draft Background Document for Glass Wool Fibers: Special Purpose Fibers and Hazard Classification.*"¹ JM also participated in the Expert Panel meeting and delivered a presentation entitled "*Distinguishing Special Purpose Glass Fibers.*" We enclose a copy of that presentation with this letter.

At the outset we note that JM is a member of and endorses the comments submitted by the North American Insulation Manufacturers Association ("NAIMA").

JM agrees that the Expert Panel's recommendation to delist glass wool is consistent with both the strong weight of scientific evidence and the findings of several authoritative scientific bodies, including the International Agency for Research on Cancer ("IARC"), the Agency for Toxic Substances and Disease Registry ("ATSDR"), and the U.S. National Academy of Sciences ("NAS"). JM also notes that over the past twenty-plus years, these authoritative bodies have recognized that insulation glass wools and special purpose fibers can, and should, be distinguished. NAIMA's previous comments to NTP provided a detailed summary of how various organizations, including the World Health Organization ("WHO"), the American Conference of Governmental Industrial Hygienists ("ACGIH"), the International Labour Organization ("ILO"), IARC, and ATSDR, have

¹ See, <http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Ray20090522.pdf> and <http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Bauer20090522.pdf>

separated glass wool into two separate categories.² Accordingly, the Expert Panel's careful conclusions describing two categories of glass wool are consistent with the international scientific community's characterization of glass wool and the extensive scientific data.

JM also agrees with the physical characteristics established by the Expert Panel to distinguish special purpose fibers of concern from other glass fibers. Specifically, the Expert Panel set forth the following physical characteristics for those special fibers of concern:

. . . longer, thinner, less soluble fibers (for example, $\geq 15 \mu\text{m}$ length with a k_{dis} of $\leq 100 \text{ ng/cm}^2/\text{h}$) . . .³

These characteristics are entirely consistent with the extensive data on both the importance of long fibers as well as the relationship between fiber durability *in vitro* (as measured by K_{dis}) and potential biological activity.⁴

These characteristics are also sufficiently specific that they will guide JM and other manufacturers and importers of special fibers of concern as we fulfill our product stewardship responsibilities and maintain compliance with the labeling and other requirements of the OSHA Hazard Communication Standard. As we pointed out in our comments to the draft background document and as the final background document notes,⁵ there are several other manufacturers of various special fibers of concern, including Evanite, Lauscha and UPF (United Pacific Fiberglass).

Thank you for the opportunity to submit these comments.

Sincerely,

Signed

Bruce D. Ray
Director, Governmental and Regulatory Affairs
Associate General Counsel

Enclosure

cc: Angus Crane, NAIMA

² See, http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/june/Mentzer20090522.pdf?bcsi_scan_7909DC0819E730E8=0&bcsi_scan_filename=Mentzer20090522.pdf (May 22, 2009)

³ Glass Wool Fibers Expert Panel Report, Part B – Recommendation for Listing Status for Glass Wool Fibers and Scientific Justification for the Recommendation at pages 1 – 2.
http://ntp.niehs.nih.gov/Ntp/roc/twelfth/2009/june/GWF_PartB.pdf

⁴ Maxim, L. D., Hadley, J. G., Potter, R. M., and Niebo, R., "The role of fiber durability/biopersistence of silica-based synthetic vitreous fibers and their influence on toxicology," *Regulatory Toxicology and Pharmacology*, 46 (1): 42-62 (2006).

⁵ Report on Carcinogens Background Document for Glass Wool Fibers (September 9, 2009) at pages 4 – 5. http://ntp.niehs.nih.gov/ntp/roc/twelfth/2009/June/GWF_Final_Background%20Document.pdf